

Development of Safe Harbor Levels

Cal/EPA

**Office of Environmental Health
Hazard Assessment**

**Reproductive and Cancer Hazard
Assessment Section**

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Introduction

Development of Proposition 65 safe harbor levels

- No Significant Risk Levels (NSRLs) for carcinogens
- Maximum Allowable Daily Levels (MADLs) for chemicals causing reproductive toxicity

OEHHA seeking input on ordering chemicals for assessment



History

1988 Regulations guiding the development of safe harbors adopted (22 CCR §12701-3, §12801-3)

1988 - 1992 Safe harbors issued on >200 chemicals (22 CCR §12705 & §12805)

1992 Regulatory guidance establishing 3-tiered NSRL development (22 CCR §12705(b), (c), & (d))

Dec.1992 Settlement Agreement requiring:

- updating of priority list
- NSRL development



Tiered Process for NSRL Development

NSRLs may be based on:

- *De novo* assessment by OEHHA
- Assessment conducted by another California state or federal agency
- Expedited assessment by OEHHA



Current Status

NSRLs

- 222 adopted in regulation:
 - 42 *de novo*,
 - 38 from other programs
 - 140 expedited
 - 2 trace elements
- 57 drafts released

MADLs

- 3 adopted in regulation
- 5 drafts released



Proposition 65 Chemicals without Safe Harbor Levels

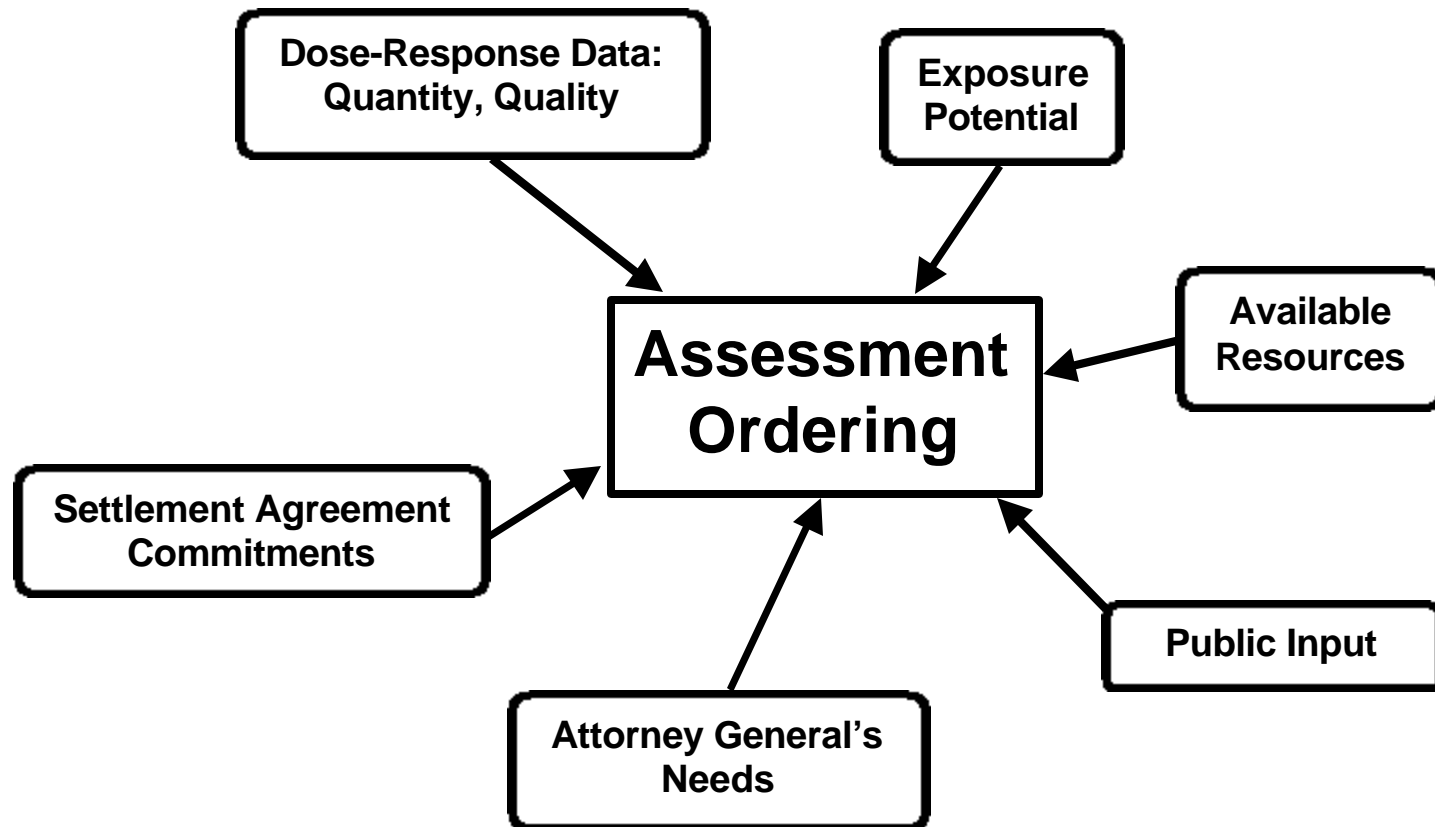
~240 Carcinogens

~250 Chemicals that cause reproductive
toxicity

OEHHA committed to developing
20 - 35 Safe Harbor levels annually



Factors for Ordering Chemicals for Assessment



Priorities for Safe Harbor Development

NSRL priorities

- First priority
- Second priority
- Third priority
- Fourth priority

MADL priorities

- First priority
- Second priority
- Third priority



Safe Harbor Development

